

U.S. Patent Application Serial No. 09/901,572  
Amendment filed November 15, 2004  
Reply to OA dated July 13, 2004

### **REMARKS**

Claims 4, 5, 9-18 and 20 are currently pending in this application. Claims 5, 9, 10, and 12-16 have been amended in order to more particularly point out, and distinctly claim, the subject matter to which the applicants regard as their invention. Applicant respectfully submits that no new matter has been added. It is believed that this Amendment is fully responsive to the Office Action dated **July 13, 2004.**

**Claims 4, 5, 10-18, and 20 are rejected under 35 U.S.C. §101 because claimed invention lacks patentable utility.** (Office action paragraph no. 6)

The Examiner states that the claims do not require that the sequence encode a protein that performs any particular function. The Examiner states that “the Applicant has not provided any utility for a DNA that encodes only a modified NXB site, the claims read on inventions for which no utility has been provided.”

The rejection under 35 U.S.C. 101 is respectfully traversed.

Applicant first notes, with regard to the Examiner’s statement that “the claims do not require that the sequence encode a protein that performs any particular function,” that there is no requirement in statute or the rules that the **claims explicitly recite** a specific utility. The utility of the invention can be explained in the specification.

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In the present case, the utility of the invention is explained in the specification. First of all, the specification indicates that the DNA molecule is designed so that no N-glycosylation will occur during expression in a eukaryotic cell (page 3, line 36, to page 4, line 4). This clearly indicates utility in the use of expression to make gene products, which is a general utility known in the art. As can be inferred by the discussion on page 1 of the specification, the DNA molecules of the invention can be used in methods which represent improvements over existing methods. The claimed recombinant viruses similarly have this utility.

Moreover, claim 20 claims a vaccine, for which utility can clearly be inferred. Applicant submits that the Examiner's assertion that "the claim reads on inoperative embodiments" is an improper ground for a rejection under 35 U.S.C. 101. Applicant notes the discussion in MPEP 2107.01 II., in particular, the Federal Circuit ruling that: "[t]o violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result" (*Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412, (Fed. Cir. 1992) (emphasis added).

Reconsideration of the rejection is respectfully requested.

**Claims 1-18, and 20 were rejected in prior action under 35 U.S.C. §112, second paragraph, as being indefinite. ... (Office action paragraph no. 8)**

The rejection is overcome by the amendments to claims 5 and 12. In the claim amendments, the wording "DNA molecule derived from" has been amended in a manner consistent with the

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amendments in response to the rejection under 35 U.S.C. 112, second paragraph, in the Amendment dated April 19, 2004.

**Claims 5 and 9 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.** (Office action paragraph no. 9)

The rejection is overcome by the amendments to claims 5 and 9. In the claim amendments, the wording "DNA molecule derived from" has been amended in a manner consistent with the amendments in response to the rejection under 35 U.S.C. 112, second paragraph, in the Amendment dated April 19, 2004.

**Claims 5 and 12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.** (Office action paragraph no. 12)

The rejection is overcome by the amendments to claims 5 and 12. The wording of the last line of each claim has been amended to: "and said portion of the genome includes the DNA sequence according to SEQ ID. NO. 1 or SEQ ID NO. 2." This wording refers back to the earlier recitation of "portion of the genome" in each claim, and therefore clarifies that the claimed sequence does include the sequence of SEQ ID. NO. 1 or SEQ ID NO. 2.

**Claims 4, 5, 9-18, and 20 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.** (Office action paragraph no. 13)

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The Examiner states that:

“it is not clear whether the language ‘a DNA sequence whose sequence comprises a portion of the genome of a prokaryotic cell in which at least one region encoding’ an altered NXB site, requires that the altered NXB site be in the DNA sequence, or if the claims require only that the modification occurs in some region of the genome of which the claimed DNA sequence is a portion.”

This rejection is respectfully traversed. Claim 4 recites that the sequence of the DNA molecule **“comprises: a portion of the genome ... in which at least one DNA region encoding an NXB site ... has been altered”** (emphasis added). Therefore, the sequence of the claimed DNA molecule of claim 4 must include this portion of the genome and must include the NXB site.

The claims do not recite that the claimed DNA sequence is a portion of some other region, as the Examiner has suggested.

**Claims 5 and 12 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.** (Office action paragraph no. 15)

The Examiner states that the claims “read on any DNA from any Mycoplasma having the DNA sequence of SEQ ID NO: 1 or SEQ ID NO: 2. However, the Applicant has not identified any sequences from such Mycoplasma other than the sequences of SEQ ID NO: 1 or SEQ ID NO: 2 themselves.”

The rejection of claims 5 and 12 under 35 U.S.C. 112, first paragraph, is respectfully traversed.

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Applicant respectfully submits that the Examiner is incorrect that the claims “read on **any** DNA from any Mycoplasma having the DNA sequence of SEQ ID NO: 1 or SEQ ID NO: 2”. This statement ignores the limitation in the first clause of claim 5 or claim 12 regarding the alteration such that no N-glycosylation occurs at the NXB site.

With regard to the Examiner’s second point, the aspect of DNA “derived from a prokaryotic cell” is discussed in the specification starting on page 6. In particular, page 7, lines 1-6, states:

“The modified DNA molecule of the present invention is a DNA molecule in which at least one region among the DNA regions encoding potential N-glycosylation sites present in the gene derived from a prokaryotic cell has been modified ...”

On page 7, lines 21-25, the specification states that:

“the prokaryotic cell-derived gene to be the target of alteration is a portion of the gene that is owned by the above prokaryotic cell and that contains the gene region encoding gene products such as protein.”

Although the specification does not disclose exactly which portion of the genomic DNA of the prokaryotic cell is to be used, it can be inferred the entire “prokaryotic cell-derived gene” is present. And, since SEQ ID NO: 1 and SEQ ID NO: 2 are entire genes, the claimed DNA must include at least the entire gene. Applicant submits that it can be inferred from the specification that any portion of the genome of the prokaryotic cell containing SEQ ID NO: 1 or SEQ ID NO: 2 can be used.

**Claims 1-3, 6, 7, 10, 11, 13, 15-18 and 20 were rejected [previously] under 35 U.S.C. §103(a) as being unpatentable over the teachings of Jacobson et al. (U.S. Patent No. 5,656,485),**

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**or Saitoh et al. (U.S. Patent No. 5,871,742-of record in the October 2001 IDS) in view of the teaching of Marini et al. (Mol. Microbiol. 38: 552-64), Essex et al. (U.S. Patent 6,103,238-of record in the June 2003 IDS), Liu et al. (Prot. Exp. and Pur., supra), and further in view of the teaching of R. Parekh (Curr. Opin. Biotech. 2: 730-34). ... (Office action paragraph no. 20)**

The Examiner indicates that the rejection is maintained for pending claims 10, 11, 13, 15-18 and 20.

The rejection is overcome by the amendments to claims 10, 13, 15 and 16. In the amendments, the recited prokaryotic cell is limited to be Mycoplasma. Support for this amendment may be found, for example, in original claim 4. Applicant submits that the combination of references does not suggest this limitation in the claims. The general motivation in this rejection to modify prokaryotic genes was discussed on pages 6-7 of the Office action dated October 20, 2003, and appears to have been inferred from a combination of Parekh (page 730) and Essex et al. (abstract) with Liu and Marini. However, there does not appear to be a specific suggestion in these references for use of a Mycoplasma gene.

**Claims 8 and 14 were rejected [previously] under 35 U.S.C. §103(a) as being unpatentable over Jacobson, Saitoh, Liu, Essex, Marni, Parekh as applied to claims 10, 11, 13, 15-18 and 20 above, and further in view of Nippon Zeon Co., LTD. (EP 0905140-Nippon).**  
(Office action paragraph no. 21)

The Examiner indicates that the rejection is maintained for pending claim 14.

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The rejection is overcome by the amendment to claim 14, in which the prokaryotic cell is limited to Mycoplasma. Support for this amendment may be found, for example, in original claim 4.

Reconsideration of the rejections is respectfully requested. In view of the aforementioned amendments and accompanying remarks, claims, as amended, are in condition for allowance, which action, at an early date, is requested.

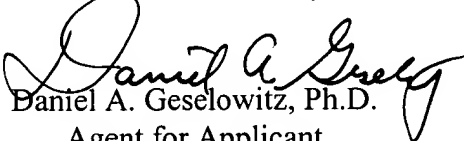
If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact Applicant's undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

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In the event that this paper is not timely filed, Applicant respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

Enclosure: Petition for Extension of Time

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